

§ 168.122

21 CFR Ch. I (4–1–13 Edition)

§ 168.122 Lactose.

(a) Lactose is the carbohydrate normally obtained from whey. It may be anhydrous or contain one molecule of water of crystallization or be a mixture of both forms.

(b) The food shall meet the following specifications:

(1) The lactose content is not less than 98.0 percent, mass over mass (m/m), calculated on a dry basis.

(2) The sulfated ash content is not more than 0.3 percent, m/m, calculated on a dry basis.

(3) The pH of a 10.0-percent m/m solution is not less than 4.5 nor more than 7.5.

(4) The loss on drying for 16 hours at 120 °C is not more than 6.0 percent, m/m.

(c) The name of the food is “Lactose” or, alternatively, “Milk sugar”.

(d) The methods of analysis in paragraphs (d)(1), (d)(2), (d)(3), (d)(4), and (d)(5) of this section are to be used to determine whether the food meets the requirements of paragraphs (b)(1), (b)(2), (b)(3), and (b)(4) of this section. The methods are contained in “Official Methods of Analysis of the Association of Official Analytical Chemists”, 14th Ed. (1984), including the 4th Supp. (1988), which is incorporated by reference in accordance with 5 U.S.C. 552(a). Copies of the material incorporated by reference may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

(1) Lactose content, sections 31.064 to 31.071, “Purity of Lactose, Liquid Chromatographic Method,” First Action, 14th Ed. (1984), pp. 583 and 584.

(2) Lactose content, sections 31.064 to 31.071, “Purity of Lactose, Liquid Chromatographic Method,” “Changes in Official Methods of Analysis,” 14th Ed., 4th Supp. (1988), p. 212. This reference recognizes the change in status of the method from first action to final action.

(3) Sulfated ash content, section 31.014, “Ash of Sugars and Sirups,” Final Action, Sulfated Ash, 14th Ed. (1984), p. 575.

(4) pH, section 14.022, “pH of Flour, Potentiometric Method,” Final Action, except that a 10-percent m/m solution of lactose in water is used for the determination, 14th Ed. (1984), p. 252.

(5) Loss on drying at 120 °C, section 31.070, 14th Ed. (1984), p. 584.

[42 FR 14479, Mar. 15, 1977, as amended at 47 FR 11834, Mar. 19, 1982; 49 FR 10103, Mar. 19, 1984; 54 FR 24896, June 12, 1989; 55 FR 8459, Mar. 8, 1990; 63 FR 14035, Mar. 24, 1998]

§ 168.130 Cane sirup.

(a) Cane sirup is the liquid food derived by concentration and heat treatment of the juice of sugarcane (*Saccharum officinarum* L.) or by solution in water of sugarcane concrete made from such juice. It contains not less than 74 percent by weight of soluble solids derived solely from such juice. The concentration may be adjusted with or without added water. It may contain one or more of the optional ingredients provided for in paragraph (b) of this section. All ingredients from which the food is fabricated shall be safe and suitable.

(b) The optional ingredients that may be used in cane sirup are:

(1) Salt.

(2) Preservatives.

(3) Defoaming agents.

(c) The name of the food is “Cane sirup” or “Sugar cane sirup”. Alternatively, the word “sirup” may be spelled “syrup”.

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[42 FR 14479, Mar. 15, 1977, as amended at 58 FR 2886, Jan. 6, 1993]

§ 168.140 Maple sirup.

(a) Maple sirup is the liquid food derived by concentration and heat treatment of the sap of the maple tree (*Acer*) or by solution in water of maple sugar (maple concrete) made from such sap. It contains not less than 66 percent by weight of soluble solids derived solely from such sap. The concentration may be adjusted with or without added